



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Hardy Diagnostics  
1430 W. McCoy Lane  
Santa Maria  
California  
93455  
USA

Holds Certificate No:

**FM 572526**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Manufacture and design of microbiological culture media, test kits and reagents, which are intended for the cultivation and identification of microorganisms and classified as in-vitro diagnostic medical devices. Distribution of a wide variety of in-vitro devices intended for such uses as prenatal screening, determining immune, autoimmune or disease status, susceptibility testing, blood grouping, detection of sexually transmissible agents and pregnancy testing.

This certificate is traceable to this company's original registration certificate number 0029255 dated December 27, 2008 and issued by SAI Global.



For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 02/24/2011

Latest Issue: 04/15/2014

Expiry Date: 05/17/2017



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Certificate No: **FM 572526**

Location	Registered Activities
Hardy Diagnostics 1430 W. McCoy Lane Santa Maria California 93455 USA	Manufacture and design of microbiological culture media, test kits and reagents, which are intended for the cultivation and identification of microorganisms and classified as in-vitro diagnostic medical devices. Distribution of a wide variety of in-vitro devices intended for such uses as prenatal screening, determining immune, autoimmune or disease status, susceptibility testing, blood grouping, detection of sexually transmissible agents and pregnancy testing.
Hardy Diagnostics 429 South Pioneer Blvd Springboro Ohio 45066 USA	Manufacture of microbiological culture media, test kits and reagents, which are intended for the cultivation and identification of microorganisms and classified as in-vitro diagnostic medical devices. Distribution of a wide variety of in-vitro devices intended for such uses as prenatal screening, determining immune, autoimmune or disease status, susceptibility testing, blood grouping, detection of sexually transmissible agents and pregnancy testing.



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An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.